



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,299	08/22/2003	Carl Ekholm	TRAUMA 3.0-435	9201

530 7590 11/01/2005
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

EXAMINER

AMARELD JR, ROBERT W

ART UNIT	PAPER NUMBER
----------	--------------

3738

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/646,299	Applicant(s) EKHOLM ET AL.	
	Examiner Robert W. Amareld, Jr.	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/22/03, 12/13/04, 3/11/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 has ambiguous wording consistent with that of a method claim and fails to particularly point out and distinctly claim where the holes are located. Particularly, the wording "bores being oriented differently for the left and right humerus in the proximal portion, except for the proximal most transverse bore" does not adequately point out the location of the holes in the second humeral nail. Additionally, claim 14 recites the limitation "a pair of humeral nails". There is insufficient antecedent basis for this limitation in the claim for a pair of humeral nails, claim 1 does not "set forth" a pair of humeral nails.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3738

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 7, 9, 15-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin (US Pat# 6210414). Lin discloses a bone fastener (interpreted as a nail) comprising a shaft (31) having a longitudinal axis (311 or 301) and having 4 longitudinal bores(34,35,36,37), being at least 3 longitudinal bores (34,35,36) in the proximal end (30), the at least 3 bores (34,35,36) being circumferentially angularly offset from each other about the longitudinal axis (301), two of the proximal transverse bores (36,37) extending at a proximal-distal angle to the longitudinal axis of the shaft, at least two bores (36, 37) being non-perpendicular to the axis, being oriented at diverging angles (all possible angles being diverging at one end and converging at the other), the wall of the nail tube being considered a thread for a screw. The proximal (34) and distal most bore extends at a proximal-distal angle from longitudinal axis 311 and form a converging angle. The proximal most(34) bore having and angle of $\sim 80^\circ$ with longitudinal axis 311, and the distal most bore (37) having an angle of $\sim 75^\circ$ with longitudinal axis 301. The bore (35) adjacent to the proximal most bore(34) is approximately perpendicular to axis 301, the offset between bore 34 and 35, being approximately 25° , as shown in Fig 1. Two bores (34, 35) are oriented perpendicular to axis 301. Additionally, two bores (38, 39), being a pair, are located in the second end of the nail, both second end bores being in a plane containing the axis of bore 34, any plane containing at least one point from each

Art Unit: 3738

axis contains the axis. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure.

Claims 1, 2, 6, 8, 9 & 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Leu US Pat# 6270499. Leu discloses a solid nail (column 2, lines 5-7) with at least 3 axially spaced, circumferentially angularly offset bores (7, 29 or 11, 27, 35) extending at a proximal-distal angle, the angle appearing to be between 75° and 90°, as shown by the extension of screw (12) through bore 35. The at least two bores (column 3, lines 1-3), at least two, encompassing 4, or, while including the head embodiment, bores 11, 27, 35, 7 & 29 constitute 4 bores in the proximal portion of the nail, the bore adjacent to the most distal bore (7) in the proximal portion (29) being perpendicular to the longitudinal axis and ~25° offset from bore 7.

Claims 1, 6, 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Huebner (US Pat# 5472444). Huebner discloses a humeral nail with a shaft having a proximal portion with five proximal bores (44a-d, 46), being at least 3 and 4, each circumferentially angularly offset with at least two of the bores extending at an angle (90°) from the longitudinal axis. The bore (44d) adjacent the most distal bore (46) is perpendicular with the longitudinal axis. The bore (44b) adjacent the most proximal bore (44a) and the most proximal bore are offset *approximately* 25°. The bore (44d) adjacent the most distal bore (46) are offset *approximately* 90°. Additionally, the bores adjacent the proximal most bore (44b) and adjacent the distal most bore (44d) are offset by *approximately* 90°.

Claim Rejections - 35 USC § 103

Art Unit: 3738

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebner in view of James (US Pat# 5489284). Huebner is explained supra. However Huebner fails to disclose two distal portion bores, the distal most bore being elongated in the direction of the longitudinal axis. James teaches the two distal bores (42,43) in distal portion 13. It would have been obvious to one of ordinary skill in the art to use two distal bores, as taught by James with the nail of Huebner such that it provides the ability to serve the accommodation of bone screws for bracing the nail.

Claims 1-5 rejected under 35 U.S.C. 103(a) as being unpatentable over Russell (US Pat# 5549610) in view of Leu. Leu is explained supra. Russell teaches a nail with the at least three longitudinal bores with proximal-distal angles to the longitudinal axis where the proximal most and distal most bores extend at a proximal-distal angles, with converging axis, where the angles of the distal most bore and the proximal most bore are approximately 75° and 80° to the longitudinal axis, consecutively. However Russell fails to disclose circumferentially angularly offset bores. Leu teaches circumferentially angularly offset bores (7,29), of which the angular offset between the distal most bore (7) and the proximal most bore (7) (not including the head embodiment) is

Art Unit: 3738

approximately 25°. It would have been obvious to one of ordinary skill in the art to use circumferentially angular offset, as taught by Leu with the nail of Russell such that it provides the ability to better transmit force from the bone the nail and vice versa.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Adam, (US Pat Appl# 09/560716, Pub# US2002/0099379)- a locking nail; Buhler, (US Pat# 6702816)- a marrow nail; Stinson, (US Pat Appl# 09/971445, Pub# US2003/0069581)- a universal nail; Sohngen, (US Pat Appl# 10/624463, Pub# US2005/0055023) – an intramedullary nail.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Amareld, Jr. whose telephone number is 571-272-6170. The examiner can normally be reached on M-F 9am - 5pm EST.

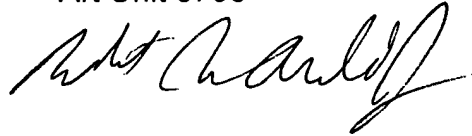
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RWA

Robert W Amareld, Jr.
Examiner
Art Unit 3738



BRIAN E. PELLEGRINO
PRIMARY EXAMINER

